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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/478,598	01/06/2000	A. Gururaj Rao	5718-16A	1892

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EXAMINER

KERR, KATHLEEN M

ART UNIT PAPER NUMBER

1652

DATE MAILED: 04/06/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/478,598	RAO ET AL.	
	Examiner	Art Unit	
	Kathleen M Kerr	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 March 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 68,69,71 and 75-79 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 68,69,71 and 75-79 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Application Status

1. In response to the previous Office action, a Final rejection (mailed on February 10, 2004), Applicants filed a response and an after-final amendment received on March 25, 2004. Said amendment cancelled Claims 58, 60-65, 67, 82, 97-105, and 125 and amended Claims 68, 69, and 71. Thus, Claims 68, 69, 71, and 75-79 are pending in the instant Office action and will be examined herein.

The **finality** of the previous Office action is **withdrawn** based on the new grounds of rejection set forth herein.

Priority

2. As previously noted, the instant application is granted the benefit of priority for the U.S. non-Provisional Application No. 08/988,015 filed on December 10, 1997.

Withdrawn - Claim Objections

3. Previous objection to Claim 68 for depending from a rejected claim is withdrawn.

Withdrawn - Claim Rejections - 35 U.S.C. § 112, first paragraph

4. Previous rejection of Claims 67, 82, and 125 under 35 U.S.C. § 112, first paragraph, enablement, is withdrawn by virtue of Applicants' cancellation of said claims.

5. Previous rejection of Claims 69, 75-79, 82 and 97-105 and 125 under 35 U.S.C. § 112, first paragraph, enablement, is withdrawn by virtue of Applicants' cancellation of said claims.

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6. Previous rejection of Claims 67, 82, and 125 under 35 U.S.C. § 112, first paragraph, new matter, is withdrawn by virtue of Applicants' cancellation of said claims.

Withdrawn - Claim Rejections - 35 U.S.C. § 102

7. Previous rejection of Claims 58, 61, 62, and 67 under 35 U.S.C. § 102(b) as being anticipated by Falco *et al.* (USPN 5,559,223) is withdrawn by virtue of Applicant's cancellation of said claims.

Withdrawn - Claim Rejections - 35 U.S.C. § 103

8. Previous rejection of Claims 58, 60-62, 67, 71, 97-102 and 125 under 35 U.S.C. § 103(a) as being unpatentable over Dyer *et al.* in view of Goldberg is withdrawn by virtue of Applicant's cancellation and/or amendment of said claims.
9. Previous rejection of Claims 63-65 and 103-105 under 35 U.S.C. § 103(a) as being unpatentable over Dyer *et al.* in view of Goldberg and in view of Arnold *et al.* is withdrawn by virtue of Applicant's cancellation of said claims.

NEW ISSUES

Claim Objections

10. Claim 68 is objected to for lacking specific reference to the appropriate protein, in the amended claim. In step a, "said protein" should be ---VSP β ---. Also, in line 3 of step a, "in said protein" can be deleted for easier reading.

Claim Rejections - 35 U.S.C. § 112

The following is a quotation of the second paragraph of 35 U.S.C. § 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

11. Claims 68, 69, 71, and 75-79 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear if VSP β is exactly SEQ ID NO:1, a 218 amino acid sequence from *Glycine max*, and no other protein. No others are disclosed in the specification; however, vegetative storage protein (vsp) is a generic term for these types of proteins. If only making mutations in SEQ ID NO:1 is intended, such limitation in the claims is required for clarity.

12. Claims 68, 69, 71, and 75-79 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claim language is confusing because the specification focuses on altering the amino acid composition AND maintaining native conformation and activity (see page 4, lines 29-30); the instant claims are drawn to simply altering amino acid sequences and assessing (without any requirement for maintaining) native conformation. Such basic criteria are met when a protein is mutated and purified with polyclonal antibodies, for example, wherein the native conformation need not be maintained as long as particular epitopes are maintained. While the combination of mutation and maintaining native conformation is implied in the language of the claims and from the specification, it is unclear if such maintenance is a clear limitation of the claimed methods. Clarification is required.

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13. Claims 68, 69, 71, and 75-79 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The phrase “set of antibodies capable of binding with the native protein, wherein said antibodies recognize the native conformation of said protein” is redundant and wordy rendering the language confusing. The intent, as is clear from the specification, is that the set of antibodies specifically recognize the native protein conformation; the “capable” phrase appears unnecessary. Clarification is required.

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

14. Claims 68, 69, 71, and 75-79 are rejected under 35 U.S.C. § 112, first paragraph, new matter, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The concepts of percent change are not supported in the specification as originally filed (see pages 7-8).

In Claim 68, the concept is altering VSP β in essential amino acids by at least 5%; however, generic altering (not limited to increasing) is described to include “at least about 10%...20% or even up to about 30% or about 40%” (see pages 7-8, lines 30-3).

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In Claim 69, the concept is increasing VSP β in essential amino acid content by at least 5%; however, increasing is described to include “at least about 5-about 10%...about 10-about 20% ...about 20-about 40%” (see page 7, lines 25-29).

The Examiner suggests amending the claims to either altering at least 10% and/or increasing to at least 5-10%.

15. Claims 68, 69, 71, and 75-79 are rejected under 35 U.S.C. § 112, first paragraph, written description, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The instant rejection is based on two concepts: (1) the lack of an upper boundary on the alteration in the protein's structure and (2) set of antibodies that recognize native conformation.

To satisfy the written description aspect of 35 U.S.C. § 112, first paragraph, for a claimed genus of methods, it must be clear that: (1) the identifying characteristics of the claimed methods have been disclosed, e.g., structure, physical and/or chemical characteristics, functional characteristics when coupled with a known or disclosed correlation between function and structure, or a combination of these; and (2) a representative number of species within the genus must be disclosed.

The specification discloses a single example of the claimed methods on pages 19-20 wherein VSP β is altered with the addition of 18 additional methionines (that is an increase in essential amino acid content of 8.3%). This mutant, VSP β -met10, was then able to bind “VSP-

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specific conformational monoclonal antibodies” in a similar fashion to wild-type; it must be assumed that these antibodies are from the panel of 12 monoclonal antibodies described on page 13 that bind soybean VSP (α or β is not noted) (see page 13). It is then noted that this “**suggests** that VSP β -met10 **may be** correctly folded” (emphasis added) (see page 20).

While this example is adequate written description of a method that increases the methionines in VSP β by a limited amount, for example, about 10%, this example is not adequate description for a method that changes the amino acid content by as much as 90 or even 100%.

This example describes a set of antibodies that recognize epitopes on both the wild type VSP β and the VSP β -met10 mutant; this example does not describe a set of antibodies that recognize the native conformation of the protein. The fact that these epitopes are recognized can be indicative of native conformation as evidenced by the “suggests” statement made in the specification on page 20. Thus, the language is limiting only on the function of the antibodies, not the structure, and this function does not necessarily have even a single representative species in the specification.

For these reasons, the instant claims lack adequate written description.

Conclusion

16. Claims 68, 69, 71, and 75-79 are rejected for the reasons identified in the numbered sections of this Office action. Applicants must respond to the objections/rejections in each of the numbered sections in this Office action to be fully responsive in prosecution.

The instant Office action is **non-final**.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathleen M Kerr whose telephone number is (571) 272-0931.

The examiner can normally be reached on Monday through Friday, from 9:00am to 6pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathupura Achutamurthy can be reached on (571) 272-0928. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Kathleen M Kerr
Examiner
Art Unit 1652

April 2, 2004